



December 9, 2008

Indiana Economic Development Corporation

Cathy J. Boggs
Director
Division of Mental Health and Addiction

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Dear Ms. Boggs:

Pursuant to IC 4-22-2-28, the Indiana Economic Development Corporation ("IEDC") has reviewed the economic impact analysis for small businesses associated with rule changes proposed by the Indiana Family and Social Services Agency ("FSSA") Division of Mental Health and Addiction (DMHA) and contained in LSA Document 08-412. The proposed rule adds 440 IAC 10 concerning the operational standards for Opioid Treatment Programs ("OTP"). The rule is meant to comply with legislative changes to IC 12-23-18 authorized by P.L. 116-2008. The proposed rule gives DMHA increased authority in the regulation of Indiana OTPs and establishes mechanisms for enforcing compliance with the rules if an OTP does not comply with requirements set forth in the rules. The proposed rule establishes four main requirements. First, it requires DMHA's specific approval of OTPs and annual certification of opioid treatment facilities. Second, the rule requires an OTP in the establishment and administration of an opioid treatment program a diversion control and oversight program to identify individuals who divert opioid treatment medications from legitimate treatment use and to terminate the opioid treatment for those individuals. Third, the rule requires an OTP to submit a diversion control plan to the DHMA by February 28 each year. The plan must include patient drug testing procedures as well as establish requirements for action by an OTP after a patient tests positive for a controlled substance that is not part of the patient's treatment plan or for which the patient lacks a prescription. Finally, it requires a methodology to be used by the DMHA to determine the yearly per-patient fee to be paid by each OTP in Indiana. This fee may not exceed \$75 per patient or the DMHA's costs of implementing and administering the required minimum standard for operation of an OTP in Indiana. According to the DHMA's records there are six (6) OTPs in Indiana that may be classified as small businesses as defined by IC 4-22-2.1-4.

Cost incurred as a result of the rule will come from:

- Collection and reporting of new data points.
- Operating seven days a week instead of six days a week.
- Increased monitoring visits as a result of a new facility certification.
- Other administrative cost increases related modifying manuals, and modifying written procedures and training staff.
- Additional costs include the fees paid to the DHMA for each patient treated by the OTP to cover the costs of DMHA's implementation of and administration of minimum standard for operation of an OTP in Indiana.

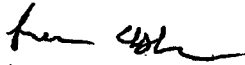
There will also be cost incurred from increasing staff to patient ratios and more frequent staff/patient interactions. Of the six (6) small businesses impacted, four (4) were interviewed by the DHMA. The businesses surveyed reported that their costs to comply with the proposed changes ranged from \$63,000 for the smallest OTP to \$390,000 for the largest OTP, based on the number of patients. Affected small businesses may also encounter a reduction in revenue due to reduced patient utilization

of Indiana OTPs associated with increased patient costs and more stringent patient requirements provided for in the proposed rule.

The impact statement prepared by FSSA indicates that this rule does not impose any requirements that are not expressly required by IC 12-23-18 and P.L. 116-2008. The IEDC does not object to the economic impact on small business associated with this rule, while the costs to small business associated with the proposed rule may in some cases be significant. Additionally, the FSSA believes that the requirements provided for by the proposed rule support the mission of promoting public health and are warranted given the demanding nature of the treatment for opioid addiction.

If you have any questions about the comments contained herein please contact me at 232-8962 or rasberry@iedc.in.gov.

Regards,



Ryan Asberry
Assistant Vice President